

REMARKS

A non-final Office Action was mailed in the above-captioned application on September 6, 2005. Claims 31-36, 45-47, 49, 50, and 53 were pending and were rejected. This Amendment and Response is submitted in response to said Office Action. A Petition for a one-month extension of time, sufficient to extend the response time from December 6, 2005, to January 6, 2006, is hereby enclosed. Applicant believes that no additional fees are necessary; however, if necessary, please charge any additional fees to deposit account No. 19-5117. Reconsideration of the instant application is respectfully requested.

The Rejection under 35 U.S.C. § 112, first paragraph

1.

The Examiner has rejected claims 31-36, 45-47, 49, 50, and 53 under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, in regards to the recitation of a genus encompassing nucleic acids/ polypeptides having at least 75% sequence identity to SEQ ID NO:4-6, 33-36, and 91, where the recited nucleic acids/polypeptides also have the property of being capable of increasing the yield in a plant, the Examiner contends that there is no support in the specification for the “increasing yield” functional language. The Examiner contends that the Specification does not provide direct and specific correlation of the claimed function (increasing yield of a plant) with the nucleic acid/protein. (Office Action, page 5).

Compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, is presumed with the burden falling on the Examiner to give reasons for a conclusion that there is a lack of correlation with the functional language recited and the disclosed or claimed method of use. MPEP 2164.02. There is a body of case law stating that if the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating by the Examiner. The key question is whether one of skill in the art would accept the model as reasonably correlating to the condition. MPEP 2164.02, *citing In re Brana*, 51 F.3d

1560, 1566 (Fed. Cir. 1995). A rigorous or exact correlation is not required. MPEP 2164.02, *citing Cross v. Iizuka*, 753 F.2d 1040, 1050 (Fed. Cir. 1985).

Applicant submits that the function of increasing yield is correlated with the nucleic acids/proteins recited sufficient to satisfy the requirements of 35 U.S.C. 112, first paragraph, in accordance with the case law discussed in the preceding paragraph. The case law specifically directs that a rigorous or exact correlation is not required. In the instant application, Applicant states on page 29, lines 16-17, “[f]rom the combination of evolutionarily significant K_A/K_S value and mapping data, one of skill in the art can reasonably conclude that . . . EG307 is a yield-related gene.” Further, Applicant summarizes the data leading to his conclusion on Specification, page 29, lines 4-15, where he reports K_A/K_S values for EG307 among different rice strains (shown in Table 1 of the instant specification) showing evolutionarily significant changes for this gene, along with mapping data showing close association of EG307 with a gene known to increase yield.

It is well-accepted in the art that where sequences are very tightly linked, then the two sequences may be associated with each other. In other words, the two sequences may be involved in regulating the phenotypic trait. Here, the close association of EG307 with a gene known to increase yield leads one of skill in the art to conclude that these genes are likely involved in regulating the trait of increased yield. That conclusion is strengthened by the evolutionary analysis showing that EG307 has had significant positive selection in domestic rice as opposed to ancestral rice. One of the hallmark changes in domestic rice versus ancestral rice is, of course, increased yield. Applicant submits that when the data is taken together, a skilled artisan would conclude that there is a correlation between EG307 and increased yield. Accordingly, Applicant submits that the correlation between EG307 and increased yield is more than sufficient to satisfy the requirements of 35 U.S.C. 112, first paragraph, especially in view of the case law stating that a rigorous or exact correlation is not required. The Examiner is respectfully requested to provide any evidence in his possession that this model does not correlate with the function described by Applicant. Accordingly, Applicant respectfully requests withdrawal of this rejection for Claims 31-36, 45-47, 49, 50, and 53.

2.

The Examiner also contends, on page 5 of the Office Action, that “there is no basis for a genus of nucleic acids/polypeptides having at least 75% sequence identity (or any other % identity) to any of the recited SEQ ID NOs. As pointed out previously, such a genus is vast . . .” Applicant believes that this rejection was made by the Examiner in a previous Office Action. Applicant addressed arguments related to this rejection in Applicant’s January 31, 2005 Response, and herein renews his traversal of this rejection.

Applicant submits that the reasoning of the rejection does not take into account the disclosure provided in the specification. Furthermore, the case citations upon which the rejection relies (*Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016, and *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997)) are distinguishable from the instant case in that they relate to fact patterns where no nucleic acid sequence was provided. In contrast, in the instant case, numerous nucleic acid sequences and polypeptides from several rice and corn species are provided, as well as the actual methods used for isolating them. Similarly, in *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (BPAI 1993), it was held that the disclosure of one bovine sequence lacked written description for the broad class. In contrast, the instant application contains numerous sequences from various organisms. Thus, the case citations are distinguishable from the instant case in that Applicant provides detailed information concerning the identity, relevant structural and physical characteristics of EG307 polynucleotides and peptides in the instant specification, as explained in more detail below.

The pending claims refer to the use of a genus of polypeptides and polynucleotides related to (i.e., bearing structural and functional similarity to) *O. sativa* and *Z. mays mays* EG307 polypeptides, including polypeptides encoded by *O. sativa* polynucleotides or *Z. mays mays* EG307 polynucleotides, which have been isolated by Applicant. It is clear that for each claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the Applicant was in possession of the claimed

genus. A "representative number of species" means that the species which are adequately described are representative of the entire genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. See The Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (January 5, 2001) [hereinafter Written Description Guidelines]. Here, the skill and knowledge in the art is high as evidenced by the section of the specification entitled "General Procedures known in the art," at page 18, the number of commercially available tools for isolation of polynucleotides and polypeptides as described in the EXAMPLES section, and throughout the disclosure. Thus, the representative number of species needed to meet the written description requirement is minimal.

In the present case, Applicant has demonstrated the existence and identification of EG307 polynucleotides from numerous rice and corn species and ancestors. Example 10 describes the discovery of the EG307 gene in rice, and Example 13 describes the identification of EG307 in maize and teosinte using the rice EG307 sequences. The EG307 polynucleotides have been identified from several strains and cultivars of *O. sativa*, including Azucena, Nipponbare Teqing Lemont IR64, and Kasalath; strains of *O. rufipogon* including 5948, 5949, IRGC 105491, and BS7; several strains and cultivars of *Zea mays mays* including HouBai, Makkai, Min13, Pira, Sari, Smena, W22; several strains and cultivars of *Zea mays parviglumis*, including Benz, BK4, IA19, Wilkes; *Zea diploperennis*, and *Zea luxurians*. Furthermore, detailed description for each gene is provided (see pages 39-52). For example, Page 39, lines 12-27, describes the characteristics of the EG307 gene in *O. sativa* (cv. Nipponbare) including the sequences of the 3' and 5' ends of the gene, the nucleotide ranges spanning the introns and exons in the gene, the sequence of the coding region, nucleotide ranges for stop and start codons, and the sequence of the protein sequence encoded by the gene. Page 52 further describes the structural relationship between the genes from various species, including high sequence identity among the various genes and subregions of genes, and common stop codon in the 5'UTR for rice.

According to the Written Description Guidelines, the "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." Applicant submits that the detailed reduction to practice for these known species of EG307 polynucleotides and polypeptides, combined with the exemplified and well-known methods for obtaining other species in the genus

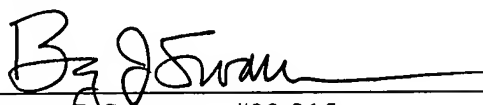
is adequate to describe the genus claimed, and that Applicant is in possession of the genus of EG307 polypeptides comprising a polypeptide encoded by (a) a polynucleotide selected from the group consisting of SEQ ID NO:4, SEQ ID NO:5, SEQ ID NO: 91, SEQ ID NO:33, SEQ ID NO:34, and SEQ ID NO:35; (b) a polypeptide encoded by a polynucleotide having at least 75% sequence identity to a polynucleotide in a); (c) a polypeptide comprising SEQ ID NO:6 or SEQ ID NO:36; and (d) a polypeptide having at least 75% sequence identity to a polypeptide of c) (as claimed).

Reconsideration is respectfully requested.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

Respectfully submitted,



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